UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,405	04/14/2004	Elaine Jaccobson	NIAD 216.2 DIV	9384

24972 7590 09/30/2009
FULBRIGHT & JAWORSKI, LLP
666 FIFTH AVE
NEW YORK, NY 10103-3198

EXAMINER	
RICCI, CRAIG D	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
09/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,405	JACCOBSON ET AL.	
	Examiner	Art Unit	
	CRAIG RICCI	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-24* is/are pending in the application.

4a) Of the above claim(s) *14,16 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13, 15, 18-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. The amendments filed 01/15/2009 were entered.

Response to Arguments

2. Applicants' arguments, filed 01/15/2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. **Claims are rejected under 35 U.S.C. 103(a) as being unpatentable over *Scivoletto* (cited in a previous Action) and *Jacobson et al* (cited in a previous Action).**

6. Instant claim is drawn to a method for increasing leptin levels in a human subject in need of skin epitheliation (as elected by Applicants) the method comprising administering to said subject a nicotinic alkyl ester (having from 12 to 22 carbon atoms in the alkyl chain of said nicotinic alkyl ester) in an amount sufficient to increase leptin levels in said subject and improve skin epitheliation.

7. As discussed in the previous Action mailed on 10/22/2008, *Scivoletto* teaches the compositions comprising nicotinamides, nicotinic acids or nicotinic esters (in particular, **methyl nicotinate** which encompasses a nicotinic alkyl ester having 1 carbon atom in the alkyl chain) for the treatment of a variety of disorders and skin conditions such as **acne**, fine lines, age spots, stretch marks, cellulite, itching, pain and itching from insect bites and stings, fungi, varicose veins, flaking and scaly skin, and **burns** including sunburn (Page 2, Lines 20-31 and Page 3, Lines 3-5). Since a person suffering from acne or a burn such as sunburn comprises a **human** subject (Page 5, Line 32) in need of skin epitheliation, *Scivoletto* teaches compositions comprising a nicotinic alkyl ester and its administration to a human subject in need of skin epitheliation to improve skin epitheliation. However, as argued by Applicant, *Scivoletto* does not teach administration of nicotinic alkyl esters having from 12 to 22 carbon atoms in the alkyl chain to a subject in need of skin epitheliation to improve skin epitheliation. Yet, Applicant is reminded that one can not show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413 (CCPA 1981) and *In re Merck & Co.*, 800 F.2d 1091 (Fed. Cir. 1986). As discussed in the previous Action,

although *Scivoletto* does not teach administration of nicotinic alkyl esters having from 12 to 22 carbon atoms in the alkyl chain to a subject in need of skin epitheliation to improve skin epitheliation, it would have been *prima facie* obvious to use such nicotinic alkyl esters in view of *Jacobson et al*. Specifically, *Jacobson et al* disclose administration of tetradecylnicotinate or octadecylnicotinate (i.e., nicotinic alkyl esters having from 12 to 22 carbon atoms in the alkyl chain; more specifically 14 and 18 carbon atoms, respectively) to a subject for the treatment of disorders such as sunburn and other skin deterioration (i.e., a subject in need of skin epitheliation to improve skin epitheliation) (Abstract and Column 5, Lines 25-34). Thus, as discussed in the previous Action, in view of *Jacobson et al*, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to administer nicotinic alkyl esters having from 12 to 22 carbon atoms in the alkyl chain (as opposed to methyl nicotinate as taught by *Scivoletto*) for the treatment of a person suffering from acne or a burn such as sunburn with a reasonable expectation of success. The skilled artisan would have been motivated to do so since *Jacobson et al* clearly establish their usefulness in the treatment of sunburn as well as related skin deterioration disorders. The simple substitution of one known agent taught for the treatment of a skin condtion such as sunburn (i.e., methyl nicotinate as taught by *Scivoletto*) for another known agent taught for the treatment of a skin condtion such as sunburn (i.e., octadecylnicotinate) to obtain predictable results is *prima facie* obvious. Furthermore, although *Scivoletto* does not recognize the increase in leptin levels as a result of the method, as previously discussed, modulation of leptin level is an underlying biological mechanism which is asserted would necessarily have occurred according to the *prima facie* obvious method. Merely discovering and claiming a new benefit of an *old* process cannot render the process again

patentable. *Verdegaal Bros., Inc. v. Union Oil Co. of Calif.,* 814 F.2d 628 (Fed. Cir.), cert. Denied, 484 U.S. 827 (1987). As in *Verdegaal Bros., Inc. v. Union Oil Co. of Calif.,* the burden of proof is limited to establishing that the prior art disclose the same process. There is no additional burden of proving that the prior art recognized the agents of the process functioned in modulating leptin levels, that result was inherently performed by the administration of agents in the disclosed process, and, thus the prior art process teaches the claimed invention. See *In re Woodruff*, 16 USPQ2d 1934 (Fed. Cir. 1990), "a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable."

8. Applicant, however, traverses. Applicant argues that "[t]here are issues with respect to the administration of nicotinic acid alkyl esters where the ester is too short" including "the problem of dilation… the redness and flushing associated with vasodilation leads to compliance issues" (Applicant Argument, Page 5). Applicant then concludes that "[t]his being the case, one of ordinary skill in the art would not regard *Scivoletto* as teaching anything beyond its limited teaches [sic]. Combination with *Jacobson et al* is certainly contraindicated" (Applicant Argument, Page 5). Applicant's conclusion is unclear since the skilled artisan, recognizing the defects associated with administration of nicotinic acid alkyl esters where the ester is too short would thus be motivated to administer nicotinic acid alkyl esters which do **not** cause vasodilation. Considering that *Jacobson et al* specifically teach that administration of tetradecylnicotinate "does not result in vasodilation" (Column 22, Lines 30-31), it would have thus been *prima facie* obvious to administer tetradecylnicotinate in place of methyl nicotinate in the invention taught by *Scivoletto*. The skilled artisan would have done so in order to overcome the known problems associated with nicotinic acid alkyl esters where the ester is too short with a

reasonable expectation that tetradecylnicotinate (i.e., a nicotinic alkyl ester having from 14 carbon atoms in the alkyl chain) would successfully do so. Accordingly, Applicant's argument is not found persuasive. As such, the rejection of claims 13, 15 and 18 is maintained.

9. Applicant does not further traverse the rejections of claims 19-21 which are thus also maintained as follows: (a) as to instant claim 19, *Jacobson et al* teach oral administration; (b) as to instant claim 20, both *Scivoletto* and *Jacobson et al* teach topical administration; and (c) as to instant claim 21, a mixture of different compounds would maximize the therapeutic effectiveness and, furthermore, *Jacobson et al* specifically teach the administration of a ***combination*** of nicotinic alkyl esters (Column 5, Line 28).

10. New claims 22-24 are drawn to the method of claim 13 wherein the nicotinic alkyl ester is administered in an amount ranging, most specifically, from about 0.4 g to about 5 g/day/70 kg of body weight. Although neither *Scivoletto* nor *Jacobson et al* specifically disclose the recited dosage range, determining the optimal dosage range would have been obvious to a person of ordinary skill in the art at the time the invention was made. Indeed, as acknowledged by Applicant in the instant Specification, "[t]he dose can and will vary" (Page 7, Line 25) and, as disclosed by *Jacobson et al*, "[d]etermination of the effective amounts is well within the capability of those skilled in the art" (Column 13, Lines 1-3). Accordingly, since it would have been *prima facie* obvious to determine the optimal dosage range via routine experimentation, and since there is no assertion that the recited ranges are critical or provide unexpected results, instant claims 22-24 are rejected. See *In re Aller*, 220 F.2d (CCPA 1955) which notes that "is it not inventive to discover the optimum or workable ranges by routine experimentation" wherein the general conditions of a claim are disclosed in the prior art.

11. Additionally, Applicant argues that "the claims of the '234 patent were all patentable over all the references cited in this current action" (see Remarks 7/2/2008 p. 5). Accordingly, if the '234 patent was found patentable over the same set of references made of record in the instant case, and the current application is subject to double patenting issues, then it cannot be obvious over the same prior art. This is not convincing because each application is evaluated on its own merits.

Double Patenting

12. Claims 13, 15 and 18-21 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,750,234. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to a method of increasing leptin levels and alleviating a condition alleviatable by increasing leptin levels by administering a nicotinic acid alkyl ester containing 12 or 14 carbon atoms. The '234 patent defines improved skin epitheliation as a condition alleviatable by increasing leptin levels by administering nicotinic acid or a nicotinic acid ester (see col. 5, line 29).

Conclusion

The new ground(s) of rejection presented in this Office action are necessitated by Applicant's amendments to the claims. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRAIG RICCI whose telephone number is (571) 270-5864. The examiner can normally be reached on Monday through Thursday, and every other Friday, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CRAIG RICCI/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614